

Notice of Allowability

Application No.

10/650,025

Examiner

Phyllis G. Spivack

Applicant(s)

BACOPOULOS ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to November 15, 2005.
2. ☒ The allowed claim(s) is/are 1,8-24,26-40 and 46-67.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 11-15-05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other The drawings are accepted.

REASONS FOR ALLOWANCE

A request for Continued Examination (RCE) and Amendment filed November 15, 2005 are acknowledged. Claims 2-7, 25 and 41-45 are canceled. Claims 1, 8-24, 26-40 and 46-67 remain under consideration.

Information Disclosure Statements filed June 23, 2005 and November 15, 2005 are further acknowledged and have been reviewed.

An objection under 35 U.S.C. 132 that previously asserted the introduction of new matter relating to the recitation "and/or the anti-cancer agents" is withdrawn. A review of the specification on pages 16 through 17 and page 46, lines 21-26, supports both "and" and "or" options.

Claims 1, 2, 8-40 and 46-61 remained rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over Jackson et al., US 2003/0161830. It was asserted Jackson teaches the administration of modulators of human histone deacetylases for use in the treatment of cancers. Both the compound suberoylanilide hydroxamic acid (SAHA) and mesothelioma are specifically disclosed.

Applicants argue Jackson does no more than provide two laundry lists. There is no working example demonstrating effectiveness of SAHA in treating mesothelioma. There is no expectation of success, particularly in view of the well recognized difficulty in treating mesothelioma. There is an insufficient teaching to guide a skilled artisan to the subject matter of the present claims. The rejection of record under 35 U.S.C. 103 is withdrawn.

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There is no motivation or suggestion to modify the teachings of the prior art and reach the presently claimed subject matter. Claims 1, 8-24, 26-40 and 46-67 are allowed in view of the contemporary knowledge of the art.

Examiner's Amendment

The present title is deleted and -- Methods of treating mesothelioma with suberoylanilide hydroxamic acid -- is inserted therefor.

The present Abstract is deleted and --

Methods for treating mesothelioma comprising administering the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA) are disclosed.
-- is inserted therefor.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585.

The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "Phyllis Spivack". The signature is written in a cursive, flowing style.

December 5, 2005

Phyllis G. Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER